International Longevity Center - USA

Prepared Testimony of

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Thank you very much for the opportunity to appear at this hearing highlighting the problem of ageism in our nation's health care system. My comments today will focus on the underrepresentation of older persons in clinical trials. Clinical trials are the processes that have been established to test the safety and efficacy of new drugs and treatments.

Unfortunately, people aged 65 and over are woefully underrepresented in or even excluded from these trials, despite the fact that they are the ones who generally take the most medications. The result is a lack of understanding of how drugs and treatments will work in older persons, which can lead to adverse reactions and inappropriate dosages or treatments, and the misperception that older people cannot tolerate or benefit from new drugs and procedures. As Congress debates the addition of a prescription drug benefit for Medicare beneficiaries, it becomes increasingly important that we have a proper understanding of how drugs affect the older population.

Today I will discuss the lack of representation of older persons in clinical trials in more depth, explore some of the reasons why this is the case, and offer some suggestions to increase their participation. The current situation is reflective of ageism in the health care system and is unacceptable. The underrepresentation of older persons in clinical trials is well documented. Three extensive studies highlight the problem particularly well. One study involving over 16,000 people in cancer clinical trials found that only 25% of the enrollees were 65 and over, although this population accounts for over 60% of all cancer cases. The trials involving breast cancer treatments were particularly dramatic – with only 9% of participants 65 and over, while women that age account for almost half of all breast cancer cases.

Another study of clinical trials focused on treatments for heart disease and also found that older people were not well-represented in such trials, or were even excluded. Moreover, this problem is exacerbated as the population grows older. For example, the study found that between 1991 and 2000, only 9 percent of patients enrolled in clinical trials were 75 and over, but almost 40 percent of people who suffer heart attacks are in this group. So, we really don't know the effectiveness of all these new cholesterolreducing drugs on older people!

Most recently, a large study conducted by RAND looked at participation in clinical trials funded by the National Cancer Institute (NCI), totaling over 59,000 patients from 1997 to 2000, which also confirmed that older people are underrepresented in clinical trials relative to their disease burden. This study also analyzed the criteria that exclude older people and found that such exclusions had a significant impact on the low participation.

Relaxing the exclusions would significantly increase articipation by older people. This lack of representation increases the likelihood of adverse drug reactions and inappropriate treatments. Older people tend to be more complex medical cases, involving multiple chronic conditions and medications and they commonly exhibit responses to medications that differ from those of younger patients, with people 85 and older particularly sensitive to typically prescribed drug dosages. It has been estimated by the National Center for Health Statistics that medication problems may be involved in as many as 17 percent of hospitalizations of older Americans annually, and another study by the GAO has estimated that drug misuse by older persons costs approximately $20 billion a year in hospital stays.

In addition, the lack of older people in clinical trials can lead physicians to make an assumption that their older patients are unable to tolerate a specific treatment and will simply not make it an option. This ageist view of older people has persisted despite a significant body of evidence, dating back to the 1960s, that older people can tolerate powerful drugs and interventions to treat cancers and other diseases and to improve quality of life. Indeed, there is no reason to assume that a person would not benefit from a drug or treatment based simply on his or her age.

There are several reasons why older people are not appropriately represented in clinical trials.

1. There is an ageist misperception that older people do not want to participate in such trials or are less likely to adhere to the research protocol. However, evidence suggests that older people can be successfully recruited and are compliant subjects in clinical trials. Moreover, with more than 35 million people aged 65 and over, a large pool of potential quality subjects is available.

2. Researchers may exclude older people, many with multiple conditions, because these subjects can make it harder to interpret the results or because they are afraid the patients may suffer negative effects. Yet people with complicated medical histories are common today, and we must learn something about older people as they live and age. Trying to "protect" them from the fruits of research is unrealistic, counterproductive, and ageist.

3. Practicing physicians may not refer older patients to clinical trials, erroneously assuming that these individuals would not receive any benefit or be effective participants. This misperception that older people can not handle the treatments associated with clinical trials is ageist, and as previously noted, not based on any evidence.

4. There are no regulatory standards governing the inclusion of older persons in clinical trials, as there are for women and minorities.

5. There is some confusion about Medicare coverage of health-care costs during clinical trials, though this has been somewhat lessened by an Executive Order clarifying Medicare payment policy to specifically allow for the reimbursement of routine patient care costs of clinical trials (such as office visits and tests).

6. The high cost of traveling to receive the treatments and other transportation related barriers preclude older persons from being able to effectively participate in trials.

So what can be done?

There are a variety of initiatives that can be undertaken to increase the participation of older persons in clinical trials. This includes efforts by both the government and by private organizations.

I would like to briefly discuss one comprehensive way to address the current lack of representation, which involves taking a fresh look at the clinical trials system. This would entail the creation of a national clinical trials and evaluation center, which would actually consist of several centers around the nation, perhaps organized similar to how HHS is organized into 10 different regions. This would be an entity focused solely on conducting clinical trials. It could be funded by those institutions that are already engaged in sponsoring clinical trials, such as the federal government, the pharmaceutical/medical industry, academia, and others. The benefits would be a more efficient, cost-effective, centralized approach with consistent standards, benefiting all parties involved. This could also enhance efforts to strengthen Phase IV clinical trials, which is basically postmarketing surveillance. Better post marketing surveillance is critical in detecting adverse drug events in the older population, given all the complicating factors associated with them. It would also help us better understand the effectiveness and cost-effectiveness of different drugs that treat the same condition. This would greatly complement any effort to increase representation of older people in clinical trials. The ILC is planning on producing an Issue Brief focused specifically on this issue in the next several months.

Other possible ways to address the lack of representation of older persons include:

1. Enacting legislation encouraging more appropriate representation of older persons in clinical trials, as has been done for women and minorities.

2. Exploring the feasibility of legislation to motivate drug makers to test medications and devices on older persons, similar to what is done to encourage pediatric studies.

3. Advocacy groups for older people should highlight the importance of clinical trials - disseminating information to their members and encouraging them to enroll.

4. Public awareness campaigns could be initiated to alert older people and their families to the existence of clinical trials and how to participate in them. Medicare could incorporate this information in its annual communications with beneficiaries, the Administration on Aging could incorporate it into a variety of its programs, and the National Institute on Aging could also be effective in highlighting the issue.

5. Programs could be established at the local level to assist older participants in clinical trials to travel to the site, provide moderate stipends, and explore ways to increase the use of community-based sites, which are more accessible.

6. Last, but certainly not least, exposing all physicians to the field of geriatrics during medical school would dispel many of the myths among medical students about older people, promote the understanding that the older population is diverse and dynamic, heighten the sensitivity of those who become clinical research investigators to the need to include older people when designing clinical trials, and increase the likelihood that practicing physicians will recommend to their older patients that they enroll in them.

In order to ensure that older people receive appropriate, evidence-based medical care, it is critical that they be better represented in clinical trials of drugs and treatments. The simple fact is that all drugs need to be tested in all populations that might be taking the drugs. The ILC has published an Issue Brief entitled "Clinical Trials and Older Persons: The Need for Greater Representation," on which my testimony is based. There are copies of this Issue Brief on the table and on our website.

Thank you again for this opportunity to discuss this important issue. I am happy to answer any questions you may have.